

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Director to determine under subsections (a) and (b) of 35 U.S.C. 156 the eligibility of a patent for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If an application for extension of patent term is incomplete under this section, the Office will so notify the applicant. If applicant requests review of a notice that an application is incomplete, or review of the filing date accorded an application under this section, applicant must file a petition pursuant to this paragraph accompanied by the fee set forth in §1.17(f) within two months of the mail date of the notice that the application is incomplete, or the notice according the filing date complained of. Unless the notice indicates otherwise, this time period may be extended under the provisions of §1.136.

[52 FR 9394, Mar. 24, 1987, as amended at 59 FR 54503, Oct. 22, 1993; 61 FR 64028, Dec. 3, 1996; 65 FR 54680, Sept. 8, 2000; 69 FR 56546, Sept. 21, 2004]

§ 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for extension filed in compliance with §1.740 or §1.790. This determination may be delegated to appropriate Patent and Trademark Office

officials and may be made at any time before the certificate of extension is issued. The Director or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with §1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of §1.136.

[60 FR 25618, May 12, 1995]

§ 1.760 Interim extension of patent term under 35 U.S.C. 156(e)(2).

An applicant who has filed a formal application for extension in compliance with §1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to §1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Director may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the *Official Gazette of the United States Patent and Trademark Office*. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. In no event will the interim extensions granted under this section be longer than the maximum period for extension to which the applicant would be eligible.

[65 FR 54680, Sept. 8, 2000]